

Application No.: 10/043,787

Docket No.: 466992000221

**REMARKS**

Claims 1, 4, 6-9, 13, 18, 19, 23, 24, 28-31, 36-50, 52-56 are pending in the present application. Claims 36-50 have been withdrawn from consideration. By virtue of this response, claims 1 and 6 have been amended. Accordingly, claims 1, 4, 6-9, 13, 18, 19, 23, 24, 28-31, and 52-56 are currently under consideration. Support for the amendment of claims 1 and 6 is found in the specification, *inter alia*, on page 20, lines 15-24; page 21, lines 9-25; and page 30, lines 21-27. Accordingly, no new matter has been added.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all claim amendments and cancellations, Applicant has not dedicated or abandoned any unclaimed subject matter and moreover has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional application.

**Claim rejections withdrawn**

Applicant acknowledges with appreciation the withdrawal of previous rejections to claims 1, 4, 8-9, 13, 18-19, 23-24, and 28-31 under 35 U.S.C. §112, second paragraph, and to claims 6 and 51 under 35 U.S.C. §102(b).

**Telephone interview**

Applicant thanks Examiner Iqbal Chowdhury and Examiner's supervisor Rebecca Prouty for extending the courtesy for a telephone interview on April 27, 2006 with Applicant's representative Jie Zhou, and providing helpful suggestions, which are reflected in this response. Claim rejections under 35 U.S.C. §112, first paragraph were discussed. Proposed amendment to claims 1 and 6 were discussed. Applicant has amended claims 1 and 6 as suggested by Examiner Prouty.

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**Claim rejections under 35 U.S.C. §112, first paragraph****A. Written Description**

Claims 1, 4, 6, 8-9, 13, 18-19, 23-24, 28-31, and 52-56 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

The Examiner states that the genus of mutant polypeptides required to practice the claimed method is a very large genus with the potentiality of being a highly structurally variable genus. The Examiner further states that recitation of the amino acid sequence of the protein being mutated does not provide support for structure of the modified product as the structure of SEQ ID NOS: 185-188 is being changed in an undescribed fashion. The Examiner further notes that in the instant case, there is no structural feature, which is representative of all the members of the mutant mammalian-derived SAH hydrolases recited in the claim, and the specification discloses only a few mutants of a single human placental SAH hydrolases which have the functional characteristics required.

Applicant disagrees with the Examiner that the genus of modified or mutant SAH hydrolases is insufficiently described. Applicants reiterate that the claims are supported by structural features and by functional characteristics coupled with a known correlation between function and structure. One skilled in the art can mutate amino acid residues that are directly interacting with the substrate and coenzyme, or that are adjacent to amino acid residues directly interacting with the substrate and coenzyme in the mouse, rat, and human genes to obtain mutant SAH hydrolase having the activities recited in the claims.

However, without acquiescence to the rejection, Applicant has amended claims 1 and 6, as suggested by Examiner Prouty during the telephone interview, to recite that the mutation in the SAH hydrolase is at one or more amino acid positions selected from the group consisting of 38, 53, 54, 57, 59, 80, 83, 100, 121, 131, 134, 155, 157, 158, 159, 181, 190, 191, 214, 221, 226, 235, 240, 248, 263, 269, 285, 292, 301, 309, 322, 329, 347, 351, 353, 361, 362, 379, 386, 388, 398, 401, 407,

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409, 420, 424, 425, 426, 427, 428, 429, 430, 431, and 432 in the mouse, rat, or human SAH hydrolase. Accordingly, withdrawal of this rejection is respectfully requested.

B. Enablement

Claims 1, 4, 6, 8-9, 13, 18-19, 23-24, 28-31, and 52-56 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement.

The Examiner states the specification while being enabling for a method for assaying Hcy, SAH and adenosine with a mutant SAH hydrolase wherein said SAH hydrolase comprises SEQ ID NO: 1 or any of SEQ ID NOS: 185-188 and also specific substitutions at the positions recited in claim 7 or the corresponding positions of SEQ ID NOS: 185-188, and those positions disclosed in the specification, wherein said mutant has the specific functional characteristics recited, does not provide enablement for a method for assaying Hcy, SAH, or adenosine with any mutant SAH hydrolase derived from SEQ ID NO: 1 or SEQ ID NOS: 185-188.

Applicant disagrees with the Examiner. Applicant reiterates that one skilled in the art could apply the teachings of the specification to mutate amino acid residues that are directly interacting with the substrate and coenzyme, or amino acid residues that are adjacent to amino acid residues directly interacting with the substrate and coenzyme in the mouse, rat, and human SAH hydrolase to obtain mutant SAH hydrolases having the activities recited in the claims without undue experimentation.

However, without acquiescence to the rejection, Applicant has amended claims 1 and 6, as suggested by Examiner Prouty during the telephone interview, to recite that the mutation in the SAH hydrolase is at one or more amino acid positions selected from the group consisting of 38, 53, 54, 57, 59, 80, 83, 100, 121, 131, 134, 155, 157, 158, 159, 181, 190, 191, 214, 221, 226, 235, 240, 248, 263, 269, 285, 292, 301, 309, 322, 329, 347, 351, 353, 361, 362, 379, 386, 388, 398, 401, 407, 409, 420, 424, 425, 426, 427, 428, 429, 430, 431, and 432 in the mouse, rat, or human SAH hydrolase. Accordingly, withdrawal of this rejection is respectfully requested.

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In view of the above, Applicant respectfully requests that the rejections under 35 U.S.C. §112, first paragraph, be withdrawn.

**Nonstatutory obviousness-type double patenting rejection**

Claims 6 and 51-56 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-16 of U.S. Pat. No. 6,376,210.

Without acquiescence to the rejection, Applicant respectfully notes that a terminal disclaimer over U.S. Pat. No. 6,376,210 is filed with this response. Withdrawal of this rejection is respectfully requested.

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**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 466992000221. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By 

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